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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,585	08/09/2001	Paul L. Hermonat	23355/55	5438

7590 01/27/2003

J.M. (Mark) Gilbreth  
GILBRETH & ASSOCIATES, P.C.  
P.O. Box 2428  
Bellaire, TX 77402-2428

[REDACTED] EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
1648	7

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/927,585</b>	Applicant(s) <b>Hermonat et al</b>
Examiner <b>A. R. SALMI</b>	Art Unit <b>1648</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on Dec 14, 2001.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1-87 are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input checked="" type="checkbox"/> Other: <b>SEQUENCE LETTER</b>        |

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## **DETAILED ACTION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

### ***Sequence Requirements***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. For example see pages 44, 56.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth below. Failure to fully comply with both these requirements in the time period set forth in this office action will be held non-responsive.

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***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I.     Claims 1-9, drawn to a method of screening a patient for cancer wherein the patient is negative for CIN III, classified in class 435, subclass 91.2. (1st method)  
**(Please note if this group is selected further select one sequence (primer) to be examined on the merits, and amend the claims accordingly, see below for explanation)**
- II.    Claims 10-15, drawn to a method of screening a patient for cancer, classified in class 536, subclass 24.33. (2nd method) **(Please note if this group is selected further select one sequence (primer) to be examined on the merits, and amend the claims accordingly, see below for explanation)**
- III.   Claims 16-20, drawn to a method of screening a patient for cancer for amplification of HPV16 sequence and another HPV selected from HPV18, HPV31, HPV33, HPV35, HPV45, HPV55, classified in class 435, subclass 91.33. (3rd method) **(Please note if this group is selected further select one sequence (primer) to be examined on the merits, and amend the claims accordingly, see below for explanation)**
- IV.    Claims 21-32, drawn to a method of screening a patient for cancer with a specific probe, and a second probe, classified in class 514, subclass 44. (4th method)  
**(Please note if this group is selected further select two sequences (probes) to**

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**(be examined on the merits, and amend the claims accordingly, see below for explanation)**

- V. Claims 33-41, drawn to a method of screening a patient for cancer with specific probe to HPV16 and a second probe for HPV18, HPV31, HPV33, HPV35, HPV45, HPV55, classified in class 435, subclass 6. (5th method) (**Please note if this group is selected further select two sequences (probes) to be examined on the merits, and amend the claims accordingly, see below for explanation**)
- VI. Claims 42-50, drawn to method of screening a patient for cancer with specific probe to HPV18, HPV31, HPV33, HPV35, HPV45, HPV55, in addition to second probe HPV18, HPV31, HPV33, HPV35, HPV45, HPV55, classified in class 536, subclass 23.1. (6th method) (**Please note if this group is selected further select two sequence (probes) to be examined on the merits, and amend the claims accordingly, see below for explanation**)
- VII. Claims 51-56, drawn to a method of treating a patient with antisense, classified in class 536, subclass 24.5. (7th method) (**Please note if this group is selected further select one sequence (antisense) to be examined on the merits, and amend the claims accordingly, see below for explanation**)
- VIII. Claims 57-63, drawn to a method of treating a patient with an agent, classified in class 530, subclass 300. (8th method) (**Please note if this group is selected**)

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**further select one sequence (antisense) to be examined on the merits, and  
amend the claims accordingly, see below for explanation)**

IX. Claims 64-68, drawn to a method of treating a patient with an agent, classified in class 435, subclass 345. (9th method) (**Please note if this group is selected  
further select one sequence to be examined on the merits, and amend the  
claims accordingly, see below for explanation)**)

X. Claims 69-75, drawn to a method of treating a patient with a recombinant vector, classified in class 435, subclass 320.1. (10th method)

XI. Claims 76-79, drawn to a kit for screening a patient for a cancer, classified in class 435, subclass 975. (1st product) (**Please note if this group is selected  
further select one sequence (probe) to be examined on the merits, and amend  
the claims accordingly, see below for explanation)**)

XII. Claims 80-87, drawn to a composition for treating a patient for cancer, classified in class 424, subclass 186.1. (2nd product) (**Please note if this group is selected  
further select one sequence to be examined on the merits, and amend the  
claims accordingly, see below for explanation)**)

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups IX and XI-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

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product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XII can be utilized in induction of immune response or the agent of Group IX can be utilized in an ELISA assay to detect HPV.

Inventions of Groups X and I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention of Group I is for priming cells and treating cancer while for example invention of Group I is a method of screening for cancer.

Inventions of Groups I-VII, X, XI-XII are mutually exclusive and patentably distinct products and methods each are structurally and functionally different products and methods which are substantially different. The products are made by different methods, and multiple methods have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes, in house and commercial databases, and scientific literature and would require the consideration of different patentability issues.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Upon election of Group I or II, III or etc., Applicants are additionally required to elect a Sequence or two identified by a specific sequence identification number, as indicated above as they apply to group(s). The recited sequences, i.e. probes, primers, viral sequence, etc.. have different structures one from other and the search for the sequences would be unduly burdensome. This requirement is not to be construed as a requirement for an election of species, since each of the sequence(s) recited is/are not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

1/27/2003

*An* ✓  
ALI R. SALIMI  
PRIMARY EXAMINER

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
7. Other: \_\_\_\_\_

**Applicant Must Provide:**

- An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

For PatentIn software help, call (703) 308-6856

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**